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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/612,393 | 07/03/2003 | Thomas E. Tarara | 16614-030001 | 3183 |
| 26181 | 7590 | 08/10/2005 | EXAMINER | |
| FISH & RICHARDSON P.C. PO BOX 1022 MINNEAPOLIS, MN 55440-1022 | | | GOLLAMUDI, SHARMILA S | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1616 | |

DATE MAILED: 08/10/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/612,393 | TARARA ET AL. | |
| | Examiner. | Art Unit | |
| | Sharmila S. Gollamudi | 1616 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 January 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 24-26 is/are pending in the application.
- 4a) Of the above claim(s) 1-23, 27 and 28 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 24-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

The Office Action of May 4, 2005 is hereby vacated and the following Office Action is issued.

Receipt of Election to Restriction Requirement received on March 10, 2005 is acknowledged.

Preliminary Amendment received on 1/3/03 is acknowledged. Claims 24-26 are pending in this application. Claims 1-23 and 27-28 are withdrawn as being directed to a non-elected invention.

Information Disclosure Statement

The information disclosure statement filed 5/11/04 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered. Note the IDS has been considered, only *certain* NPL documents that have not been submitted, have not been considered by the examiner.

Election/Restrictions

Applicant's election with traverse of Group IV, claims 24-26 in the reply filed on 3/10/05 is acknowledged. The traversal is on the ground(s) that applicant's have requested an interference with US patent 6,416,739. This is not found persuasive because before declaring an interference, the patentability of the claims must first be considered, i.e. "the claim should be allowable". See MPEP 2301.01 "Preliminaries to an Interference". Therefore, the instant application has four distinct inventions as discussed in the Office Action of 9/10/04 and creates an undue burden. The requirement is still deemed proper and is therefore made FINAL.

Priority

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With regard to claim 24 and 26, applicant is entitled the priority claim of provisional application 60/060337 with a filing date of 9/29/97. However, the subject matter of claim 25 does not does not have support in provisional application 60/060337 and thus is not entitled the priority claim to 9/29/97. With regard to claim 25, ammonium acetate and ammonium carbonate are entitled to the effective filing date of 9/29/98.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 26 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 25 is directed to a blowing agent selected from ammonium acetate, ammonium carbonate, and acids. Although organic substances and dispersed salts such as ammonium salts are disclosed as a blowing agent (page 27) and page 17 specifically discloses ammonium carbonate and acetate as organic solids and salt, *acids* are not disclosed as blowing agents. Applicant points to page 29, lines 15-18 for support; however the disclosure of page 29 only teaches the use of acids as pH adjusters. Therefore, the recitation of “acids” is considered new matter.

Claim Rejections - 35 USC § 102

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The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 24-25 are rejected under 35 U.S.C. 102(b) as being anticipated by US patent 4,180,593 to Cohan et al.

Cohan et al disclose a process of producing round spherical free flowing blown beads of controlled bulk density. See abstract. The process includes providing a sprayable composition, which includes an edible film, a liquid, and a blowing agent (ammonium salts: carbonate and bicarbonate). The particles are spray-dried to produce the spherical beads. See examples, column 1, lines 50-60, and column 4.

Claims 24-25 are rejected under 35 U.S.C. 102(b) as being anticipated by US patent 2,797,201 to Veatch et al.

Veatch et al disclose a process of producing hollow particles. Specifically, examples 5-7 disclose polyvinyl solutions (wall forming material) and ammonium carbonate. The solutions were spray-dried and the particles recovered.

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claim 24 is rejected under 35 U.S.C. 102 (a) and (e) as being anticipated by US 5,605,673 to Schutt et al.

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Schutt et al disclose a process of preparing a stabilized microbubble for ultrasound.

Example X spray-drying of starch (wall forming material) containing emulsions. The emulsion further contains 1,1,2-trichlorotrifluoroethane (blowing agent). Note column 22, lines 1-45.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,605,673 to Schutt et al.

Schutt et al disclose a process of preparing a stabilized microbubble for ultrasound. Example X spray-drying of starch (wall forming material) containing emulsions. The emulsion further contains 1,1,2-trichlorotrifluoroethane (blowing agent). Note column 22, lines 1-45. Schutt teaches membrane forming phase comprises surfactants or foaming agents such as starches, dextrans, gelatin, and serum albumins, among others. See column 13, lines 6-30, column 4, lines 43-47, and claim 38. Furthermore, Schutt teaches the use of albumin provides a thick shell to reduce the compressibility of the bubbles, thereby reducing their echogenicity. See column 2, lines 16-25.

Although Schutt teaches the albumin as a wall forming ingredient, Schutt only suggest its use.

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It would have been obvious to one of ordinary skill in the art at the time the invention was made to look to the guidance provided by Schutt et al and utilize the instant albumin as the wall forming material instead of the exemplified starch. One would have been motivated to do so with the expectation of similar results since Schutt not only teaches the equivalency of starch and albumin as wall forming materials, Schutt teaches albumin provides a thick shell to reduce the compressibility of the bubbles.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 24-25 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims of U.S. Patent No. 6,565,885. Although the conflicting claims are not identical, they are not patentably distinct from each other because:

Instant claim 24 is directed to a method for preparing microparticles, wherein said method comprises spray-drying wall-forming materials and wherein said method further comprises inclusion of a blowing agent in the feedstock for spray drying.

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Instant claim 25 is directed to the method according to claim 24, wherein said blowing agent is selected from the group consisting of ammonium acetate, ammonium carbonate, and acids.

Instant claim 26 is directed to the method according to claim 24, wherein said wall-forming is albumin.

US patent is directed to a method of forming a powder comprising microstructures by spray drying comprising the steps: providing a feed stock comprising a bioactive agent, surfactant, and a blowing agent wherein said blowing agent is selected from the group consisting of fluorinated compounds, nonfluorinated oils, ammonium salts, alcohols, chloroform, ethyl acetate, acetone, nitrogen, carbon dioxide, camphor, and latex wherein the ratio of blowing agent/surfactant is between 1.0-60 w/w; atomizing said feed stock to produce dispersed droplets; drying said droplets to form perforated microstructures comprising said bioactive agent and surfactant; and collecting said perforated microstructures.

US claim 34 is directed to ammonium carbonate and camphor as the blowing agent.

The instant application and US patent are directed to obvious and overlapping subject matter. Firstly, although the instant claims are directed to "microparticles" and US patent is directed to "perforated microstructures", these are considered obvious subject matter since the instant specification (page 25) discloses on that the blowing agent provides this perforated structure. Secondly, the instant specification discloses the use of surfactants as part material that forms the microstructures. Lastly, claim 25 is directed to ammonium carbonate or acetate as the blowing agent. Thus, the instant claims is directed to the broader scope without specifying the

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wall-forming material and blowing agent and US patent is directed to the narrower scope wherein the wall-forming agent is specified and the blowing agent.

Claim 24 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims of U.S. Patent No. 6,207,135 (same assignee). Although the conflicting claims are not identical, they are not patentably distinct from each other because:

Instant claim 24 is directed to a method for preparing microparticles, wherein said method comprises spray-drying wall-forming materials and wherein said method further comprises inclusion of a blowing agent in the feedstock for spray drying.

US patent is directed to a process for the production of gaseous microparticles for ultrasonic diagnosis, whose wall material is built up from polyesters of .alpha.-, .beta.-, or .gamma.-hydroxycarboxylic acids, comprising: dissolving the polyester(s) and optionally a surface-active substance in an organic solvent or solvent mixture to obtain a polyester solution, of which at least one solvent is readily water-miscible, dispersing a liquid perfluorinated compound which is not a solvent for the polymer in the polyester solution to obtain a dispersion and then dispersing the dispersion in water that contains a surface-active substance using a stirring mechanism, removing the solvent by pumping in gas and applying a vacuum to obtain a suspension, and mixing the suspension with a suitable pharmaceutically acceptable cryoprotector and freeze-drying to yield gaseous microparticles.

The instant application and US patent are directed to obvious and overlapping subject matter. Instant application requires a wall forming material and a blowing agent without specificity in the method of making the microparticles. US '135 is directed to a specific wall

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forming material and a specific blowing agent (perfluorinated compound) in the method of making the microparticles. The instant disclosure on page 22, lines 20-25, perfluorinated compounds may be utilized as the blowing agents. Therefore, the instant application is directed to the broader scope and anticipates the narrower scope of US '135.

Conclusion


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharmila S. Gollamudi whose telephone number is 571-272-0614. The examiner can normally be reached on M-F (8:00-5:30), alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on 571-272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sharmila S. Gollamudi
Examiner
Art Unit 1616

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